



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**

**WARNING LETTER**

FLA-00-60

June 12, 2000

Edward Wood Jr., Vice President  
Wood's Fishery, Inc.  
425 Angel Fish St.  
Highland View, FL 32456

Dear Mr. Wood:

We inspected your firm, located at 425 Angel Fish St., Highland View, FL on September 16, 1999 and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation, which was previously brought to your attention, causes the shrimp you pack to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Weigh/Pack/Label critical control point to control the sulfite hazard listed in your HACCP plan for frozen shrimp.


We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan or copies of monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Ken Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with the first name "Emma" and last name "Singleton" clearly distinguishable.

Emma R. Singleton  
Director, Florida District